TENTATIVE REVIEW OF IMPLEMENTATION OF TITLE VII OF THE BASIC SAFETY STANDARDS

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1 ABSTRACT

European Directive 96/29/Euratom (1) issued on 13 May 1996 should have been implemented by May 2000. This Directive "lays down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation". Title VII of the Directive introduces special provisions related to Naturally Occurring Radioactive Material (NORM).

The paper presents the answers to a questionnaire sent to technical counterparts in the 15 Member States. The objective is to make an unofficial comparison of the degree of implementation of Title VII in the different countries: has a reference level been set, did identification of work activities start, on what basis, is a specific organisation in charge of implementation of Title VII, have countermeasures been launched ?

On the basis of some answers we are able to highlight some interesting experiences: the information given can be the starting point for a discussion during the conference or a contact later on.

Of course the presentation is an opportunity to remind the work published by the Commission (guidance and studies following contract) as prepared by the Group of Experts set up under the terms of Article 31 of the Euratom Treaty.

This is a contribution aiming at the harmonisation of national regulations on the basis of the European Directive by sharing experiences, information and enhancing the dialogue in order to limit redundancy in the preparatory work that is necessary in each country.

2 INTRODUCTION

More than any other set of provisions laid down in the 96/29 Euratom Directive (1), Title VII can be defined as being a step by step process aiming to:
(a) Identify work activities involving natural radiation sources from a qualitative point of view and define those which should be considered of concern from a radiation protection point of view (quantitative point of view);
(b) Take the adequate protection measures (monitoring and adoption of specific measures).

Although this Title's provisions describe a process, which is legally binding, the practical implementation of this process is flexible enough as to allow the Member States to adopt a variety of legal and technical choices. The reviewing work of the implementation of Title VII is to be understood in that context.

Indeed, the following presentation of the results of the questionnaire aims to focus on the different solutions that have been adopted (or are in the course of being adopted) in the Member States, in the framework of the transposition process. It thus will hopefully help to share experiences in that field.

Prior to the presentation of the results however, it was felt necessary to examine Title VII provisions in order to make a distinction between binding provisions which are precise enough from others provisions which practical implementation may be different in each Member State.

3 REVIEW OF TITLE VII PROVISIONS

This review mainly insists on Articles 40 and 41 provisions, the main reason being that Article 42 is more precise and thus does not raise as many difficulties of interpretation. Indeed, the work activity (cosmic ray doses incurred during flights), the action level (arrangements taken concerning aircrew liable to be subject to exposures more than 1 mSv/year) and the main protection measures are quite clear.

However, Article 42 helps to some extent to construe Articles 40 and 41 and will be consequently used as such.
In addition, It is worth mentioning that the work done by the Article 31 Experts group on this question (Radiation Protection Document 88 (referred to as "RP 88"(2) in this paper) constitutes a useful guidance which is used as such when necessary in this paper.

3.1 Identification of concerned activities

3.1.1Definition of activities concerned: Article 40.1 refers to "a significant increase in the exposure" in the process of work activities involving natural radiation sources, which cannot be disregarded from a radiation protection point of view.
This Article clearly refers to a specific category of exposures which cannot be characterised either as resulting from "practices" which are defined in Article 2(1) or as being part of the natural level of radiation (exclusions defined in Article 2(4) which includes radon in dwellings).

Article 40 (2), a), b), c) and d) determine groups of activities which shall be taken into consideration in any case either because:
- Exposures from natural radiation sources are involved (exposures to thoron or radon daughters or gamma radiation). Examples are given in the Directive (spas, caves mines, underground workplaces and aboveground workplaces in identified areas) and in RP 88 (2);Or
- Exposures might result from a process involving naturally radioactive material during the process itself (production or storage-see Article 40(2) b)) or/and in the waste streams resulting from such a process (Article 40(2)c)). When dealing with potential exposures deriving from waste streams, the Directive essentially focuses on the members of the public which are more likely to be affected. Examples of process industries are given in RP 88 (2) (phosphate industry, rare earth involving monazite, oil and gas industry etc).Or
- Cosmic ray doses incurred during flights.

3.1.2Levels above which such activities are concerned: the same Article refers more specifically to “a significant increase in the exposure…. which cannot be disregarded (etc)”.

At first sight, the criterion used is rather vague since the range (or the value) chosen requires adaptability to a great variety of situations and, consequently offers possibilities of interpretation.

However, it must be born in mind that consistency with the general EU legal framework which applies more widely to the radiation protection field is desirable. The guidance provided by RP 88 (2) is taking this concern into account:
- The Action Level for Radon which is recommended in RP 88 represents an equivalent of an annual effective dose range of 3 to 6 mSv (between 500-1000 Bq/m3 for workplaces which is based on a 2000 hours/year occupancy and an equilibrium factor of 0.4).
It logically refers to the criterion for classifying category A (that is the dose level at which special actions are required to protect workers), even though this provision applies to practices.
- The fact that Article 42 (protection of aircrew) clearly refers to a value of 1 mSv/year is also to be taken into consideration. Although it applies in the specific case of cosmic rays doses incurred during flights, it constitutes undoubtedly a landmark which has been considered as such in RP 88 (2).

3.2 Actions required from the Member States

3.2.1 A main obligation: according to Article 40 (2), the main obligation of the Member States is to “ensure the identification by means of surveys or by any appropriate means” of work activities which may be of concern.
The binding element contained in this provision is limited to the setting up of a process of identification. Therefore, any procedure for the purpose of identifying work activities concerned (or “above-ground workplaces in identified area”) can be chosen.

Although the Directive always refers to “Member States”, it is important to underline that, for practical reasons, a competent authority should be designated in order to fulfil the said obligation.

3.2.2 An obligation which derives from the identification procedure: In so far as a type of work activity (WA) has been identified as being of concern, the Member States must draw the necessary conclusions:
- By declaring those activities as being of concern (see Article 40(3)).
- By adopting the necessary measures from a radiation protection point of view (see Article 41).

It is worth mentioning that the notion of “declaration” (which is a Member State obligation) is to be interpreted widely. It can (but does not necessarily) refer to the formal reporting procedure concerning some categories of practices (see Article 3), which responsibility rests on the undertaking.
Consequently and when referring to “declaration”, Article 40(3) main purpose is to draw the legal conclusions from the identification process. This is done by defining the type of work activities (previously identified as being of concern)

which are more likely concerned by the protection measures set in Articles 41 and 42 (“needed attention and had to be subject of control”).

3.3 Definition and implementation of protection measures:

As soon as the process of identification has been achieved, monitoring may prove necessary to provide for protection measures. At that stage, the Directive refers to the two classic ways of handling exposures of workers or of members of the public.

3.3.1Monitoring of exposures: the first paragraph of Article 41 emphasises on the monitoring of exposures in order to determine, in each particular case, whether or not protection measures are necessary. It produces two kinds of consequences:

- It requires a previous technical work (adequate measurement methods/adapted scenario of exposures to assess the corresponding doses);
- and implies that all the work activities which can be included in a type of activity “declared as being of concern”, will not necessarily require protection measures in case the results of the monitoring of exposure do not require any further steps.

3.3.2 Protection measures: Article 41 (a) and (b) refer to the adoption of all or part of the corrective measures which are applicable to intervention situations (Title IX) and to the adoption of all or part of the corrective measures which are applicable to practices (all or part of Titles III, IV, V, VI and VIII).

Indeed, it takes into account that work activities can be assimilated either (fully or partly) to practices or to interventions, depending on the type of exposures and situation involved.

In cases when the exposures resulting from natural radiation are essentially the consequences of the work activity (WA) involved (industrial activities such as phosphate industry for instance), it would be rather logical to deal with those exposures in a framework similar to the system applicable for practices. On the contrary and when such exposures are independent from the work activity involved (radon in offices for instance), those are more likely to be dealt with on the basis of the provisions applicable to intervention situations.

However useful, this kind of classification cannot be applied mechanically and that is why this Article of Title VII gives significant discretion to the Member States. Indeed, the choice of adapted protection measures in each case requires a common sense approach rather than a rigid one.

The radiation protection measures applicable to aircrew illustrate quite well the fact that the reference to protection measures applicable to practices or interventions is to be interpreted as being no more than a useful guideline.

4 RESPONSES TO THE QUESTIONNAIRE

An informal questionnaire (appendix) with 16 questions has been sent to contact people in each of the fifteen Members States (MSs).

The answers have been summarised into diagrams, which we try to comment. Interesting experiences are highlighted and discussed bearing in mind the flexibility allowed while implementing Title VII of BSS.

Note that, as written in the title, this is a “tentative” review of implementation of Title VII, meaning it is far from being exhaustive and is not an official neither legal approval of the way transposition was dealt.

This analysis aims at contributing to the harmonisation of national regulations on the basis of the European Directive by sharing experiences, information and enhancing the dialogue in order to limit redundancy in the preparatory work that is necessary in each country. Details regarding EU guidance on the implementation of BSS and on some national implementations are being presented during the symposium.

We thank each of the people who answered the questionnaire: we had a 100% rate of return!

This means that in case of “Yes / No” choice, “No” answer appears always even as a tiny mark near the vertical axis (the same for “no answer at all” for a specific question). Details corresponding to different degree of “Yes” may be given as intermediate “values” corresponding to the legend.

Such a questionnaire is difficult to answer to and also to analyse. We could not have the discussions, which would have been necessary to make the answer homogeneous: nevertheless interesting information worth sharing can be presented.

4.1 Status of communication of transposition measures

On Figure 1[1] we read that as on August 2001, only eight countries had fully communicated the legal measures supposed to transpose the BSS.
Concerning Title VII, several countries (namely Netherlands/NL, Finland/FIN and United Kingdom/UK) consider that their regulation has already taken NORM materials properly into account: this has an impact on some of the answers given.

4.2 Question n°1: Did you set a reference level of exposure?

The first step to start considering NORM could be to set a reference level of exposure that is a dose criterion above background. Although they answered “No” to Question 1 (see “Yes –“ in Q1 - Figure 2) some countries do have a rule to set a level of exposure considered as “significant increase … which cannot be disregarded…” (Q2 - Figure 3).

In Luxembourg, “reference values” are not used and the regulation refers to “limits” instead.

The 1 $mSv.year^{-1}$ value mentioned for workers (figure 3) corresponds to the recommendation given by Article 31 Experts in Radiation Protection No°88

[1] In the graphs, countries are referred to by their original acronyms in alphabetical order. Same acronyms in the text.

(RP 88) (2) and RP 95 (3). In fact some countries refer directly to this recommendation at least on a preliminary basis (see Sweden/S).

For member of population, when specified, the "significant increase" of exposure is within an interval of 0.1 to 1 mSv.year^{-1} and may vary in the same country. In NL ambient dose 10 mm depth in the body is a little less than 1 mSv effective dose.

4.3 Which type of activity should be considered?

All countries except one started formal identification of work activities (WA). To start investigating UK, FIN, NL, IRL (also I) consider the industries already mentioned in their regulation as regulated (see Y4 of figure 4) (in I the list is part of the regulation). In IRL industries are identified from the Integrated Pollution Control (IPC) license system, a list independent from RP considerations.
Otherwise, the list established is based on the "literature" without any detail. In fact numerous reference could be given and some countries refer directly to the work done on behalf of the Commission by technical Experts and the Article 31 Experts. RP 95 (3) and RP 107 (4) are respectively the guidance and the corresponding complete study establishing the reference levels of activity concentrations giving potential exposures of 1, 6 and 20 mSv.year^{-1} to employees of a wide range of industries.
As answer, the list quoted from the Italian regulation covers most of RP 88 (2)'s. table 1. Some specific materials are considered as having a potential concern: slagwool in NL, "flying-ash from thermoelectric plant, cement industries" in Greece/EL or radioactive waste originating from water purification in several countries. In FIN legislation sets a dose criterion and a U/Th mass specific activity of 0.1 kg/t (1.2 kBq U238/kg or 0.4 Th) above which WA must be notified.
In E identification is done under the framework of MARNA Project (5). In F a working group has prepared a review to prepare implementation.

4.4 Has a specific organisation been designed to implement Title VII (Question n°7)?

Nearly every country has already identified a competent authority.
They are listed in the following table and the corresponding law when it was mentioned. In D details are given in (6).

Country	Organisation		Law
B	FANC	Federal Agency for Nuclear Controls	Draft Arrêté Royal
DK	NIHR	Nat. Inst. Of Radiation Hygiene	Order n° 823 31-10-1977
D	BMU*	Bundesministerium für Umwelt	BGBl. Teil I Nr.20, 10/05/00
EL	GAEC	Greek Atomic Energy Commission	FEK 216/B/6.3.2001

E	CSN	Consejo de Seguridad Nuclear	Décret Royal 783/2001
F	IRSN In 2002	Institut Radioprotection et Sûreté Nucléaire	Ordonnance 28-03-2001 + … expecting Decree
IRL	RPII	Radiological Prot. Inst.of Ireland	Radiological Protection Act 1991 (Ionising Radiation Order), 2000
I	ANPA*	Nat. Agency for the Protection of the Environment (Dep. for Nuclear and Radiological Risk)	Legislative Decree n° 241/2000 (26.05.00)
L	Dir. Santé	Direction de la Santé	Regl. Grand-ducal 14.12.00
NL	Inspectorate	Ministry of Environment, Social Affairs, Economy	
A	-- *		
P	--		
FIN	STUK	Radiation and Nuclear Safety Authority	F. Radiation (Act or) Decree in 1992
S	SSI	Swedish Radiation Protection Institute	Ordinance 1988:295
UK	HSE	Health and Safety Executive (for workers) + Regional agencies (for registration / authorisations)	Ionising Radiation Regulations 1999 (IRR99) + Radioactive Substance Act 1993 (7)

* In addition to organisations, answers mentioned units or working groups dedicated to research… : in A, BMU; in D, BfS/SSK = Radiation protection Commission,
in I “legislation provides for a special technical body at the national level charged with elaborating guidelines, criteria and methodology for measurements exposure assessment”

4.5 Assessment of exposure (Question n°8)

The complete set of measuring methods is used: external (or “physical” for UK), internal dosimetry, with direct measurements at work places or samples analysis, and survey measurements.
Then, to establish what, if any, measures are needed to restrict the exposures of their employees, and others affected by the work activity, a risk assessment based on a comparison / screening against the “reference levels” mentioned earlier is conducted.
In UK due to the complexity of the problem, HSE is to commission research

which aims to obtain realistic data to enable employers to carry out practical assessments of radiation doses to employees from work with NORM.

4.6 How did you take into consideration the exposure of workers, the impact on members of the public? (Question n° 9 and 10)

WA being identified, undertakings must monitor, assess exposures, … then must report – register (D), use "reporting file" (Be), L specifies "medical surveillance".

In case of public exposure, "intervention" are planned in EL, a pilot restoration of phosphogypsum pile area has been implemented in E.
In I according to the exposure, the WA must be kept under control, measurements renewed (repeated) every three years (one year if exposure is between 0.8 and 1 $mSv.year^{-1}$). Above 1 $mSv.year^{-1}$ operator must submit a report and adopt "intervention measures" to keep exposures below.
Of course if undertakings fail to fulfil their obligation, the organisation is empowered to issue an order.

In Greece, the law has implemented the scale of potential annual effective dose from 1 to 6 and 20 $mSv.year^{-1}$ given in RP 95 (3): below 1 $mSv.year^{-1}$ no authorisation is needed, from 1 to 6 $mSv.year^{-1}$ the area is supervised, above 6 it is controlled and work is not permitted above 20 $mSv.year^{-1}$.

4.7 Monitoring (Question n°11, figure 5)

Extensive monitoring of exposure has started in certain countries even if BSS (and Title VII) is not yet implemented. Certain countries specified radon monitoring was concerned and may be some of the other "Yes" answers are limited to radon. Indeed work activities have first to be identified before monitoring can start and taking into consideration this new range of concerns, NL specifies they intend to "harmonise the approach in the near future". In UK, "apart from the specific requirements to monitor people, where appropriate, employers are required to monitor areas to keep exposures under review with the aim at checking the adequacy of the control measures."
For D, monitoring is described in Heft 8, 9 (6) published by Strahlen Schutz Kommission (SSK), while FIN refers to Guide ST 12.1 (8) giving details regarding the monitoring i.e. measurements intervals, type of methods to be used,…

4.8 Countermeasures (Questions n°12 to 14, figure 6)

Once again it is difficult to say if countries considered countermeasures implemented to cope with high exposures to radon in homes / workplaces or only for the work activities, if countries considered the issue according to regulation prior to transposition of Title VII or not.

In B, "reporting of existing WA has to take place (in the next) 2 years; after investigations, the FANC may require corrective measures to be carried out."
In F interventions (old watch manufactures, schools suspected of Rn contamination) have already occurred but on basis of former regulation.
In I countermeasures have not been started but the legal framework for such

operations either as “interventions” or as “practices” has been set.
In NL countermeasures are “seen more as optimisation” than as interventions: in fact the ICRP principle must be the basis for driving any action taken aiming at reducing the exposures. If the voluntary actions are not enough to reduce them below the reference values discussed earlier and prevent the legal requirements from applying, the WA may have to comply to a system equivalent to that of “practices”.

4.9 What about the future?

Q15a: When Title VII is fully implemented will new projects in the “non nuclear industry” be considered as “practices”? (figure 7)
Of course several answered “no” because they deal indeed with “work activities” (and not “practices”) but we could consider them as full “Yes”. In fact being “identified”, the “work activities” may become subject to rules equivalent to “practices”, that is … declaration, measurements, reporting, … all the elements necessary to ensure a good health protection of individuals.

The objective of certain countries is to apply to WA (natural radioactivity) a system as similar as possible to “practices” (artificial sources) but B specifies that, “in order to avoid confusion, explicit referring to practices shall be avoided as much as possible”.

Q15b: Are countries going to distinguish between “existing and new industries”? Most of the countries are not; for sake of health protection a system equivalent to “practices” should be applied to WA.
One “Yes” answer is justified in FIN because past mining activities with no known opeCONrator are considered separately and subject to intervention.

5 CONCLUSIONS

Title VII of BSS deals with work activities potentially leading to a “significant increase in exposure due to natural radiation”: it has been prepared as a flexible system

Analysis of the answers to an informal questionnaire gave a variety of them which however show similar ways for the implementation of BSS. Nevertheless, differences may be large in reference levels for the public, basis for identification of activities.

There are frequent references to EC work (RP documentation…): sometimes answers mention direct extraction of information, often their logic inspires greatly the work.

In most countries there is much a similar way to consider work activities as specific and requiring implementation of a system intermediate between what is described by BSS for practices or interventions.

As implementation is not fully completed in most countries, some of them having still research work under progress, there is still scope for discussions and progress towards harmonisation of national regulations.

6 REFERENCES

1. European Directive 96/29/ EURATOM 13 May 1996, OJ L 159 of 29.06.96, p1ff

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2. Radiation Protection 88. Recommendations for the implementation of Title VII of the European Basic Safety Standards Directive (BSS) concerning significant increase in exposure due to natural radiation sources,*1997*,ISBN92-827-5336-0 (http://europa.eu.int/comm/environment/radprot/88/88.htm)

3. Radiation Protection 95. Reference levels for workplaces processing materials with enhanced levels of naturally occurring radionuclides. *Published in July 1999,* ISBN 92-828-6616-5

4. Radiation Protection 107. Establishment of reference levels for regulatory control of workplaces where materials are processed which contain enhanced levels of naturally occurring radionuclides. *August 1999*, ISBN 92-828-6655-6

5. “Proyecto MARNA. Mapa de radiación gamma natural” Colección Informes Técnicos 5. 2000 CSN

6. D Radiation exposure at working places by natural radionuclides, Strahlenschutzkommission (SSK), Heft 10 -About Monitoring : Heft 8, 9

7. UK HSE guidance “Work with Ionising Radiation” Approved Code of Practice and Guidance, reference L121 (ISBN 0 7176 1746 7), HSE Books : 0044 1787 881165

8. FIN refers to Guide ST 12.1 giving details regarding the monitoring i.e. measurements intervals, type methods to be used,…

7 APPENDIX: THE QUESTIONNAIRE

Q1: Did you set a reference level of exposure?

Q2: What level of exposure did you (= MS for Member State) choose as “significant increase … which cannot be disregarded…”?…

Q3: Did you start “identify{ing} … the work activities which may be of concern”?

Q4: How did you organise the identification?

Q5: Has a generic list been established including, for example, a grid with two leading criteria – nature of the material used – type of activity-process involved?

Q6: How has the grid been set up, how has the process been chosen, how are they designed?

Q7: Has a specific organisation been designed to implement Title VII?
-an organisation to identify the work activities?
- an organisation to control the identified activities?

Q8: Which approach do you use to assess the exposure?

Q9: How did you take into consideration the exposure of workers involved in activities which may be of concern?

Q10: How did you take into consideration the impact on members of the public?
Q11: Have you set up specific means to monitor the exposure?

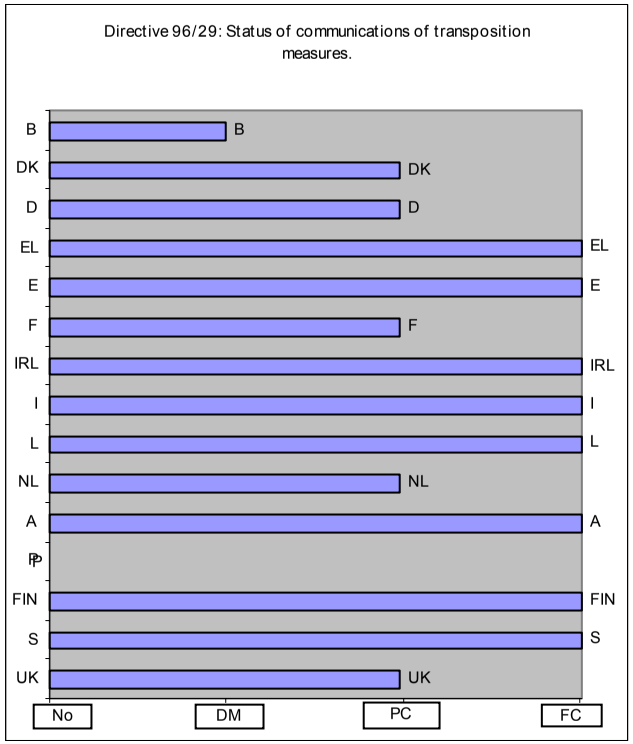
Q12: Have you started implementing countermeasures in workplaces, …?

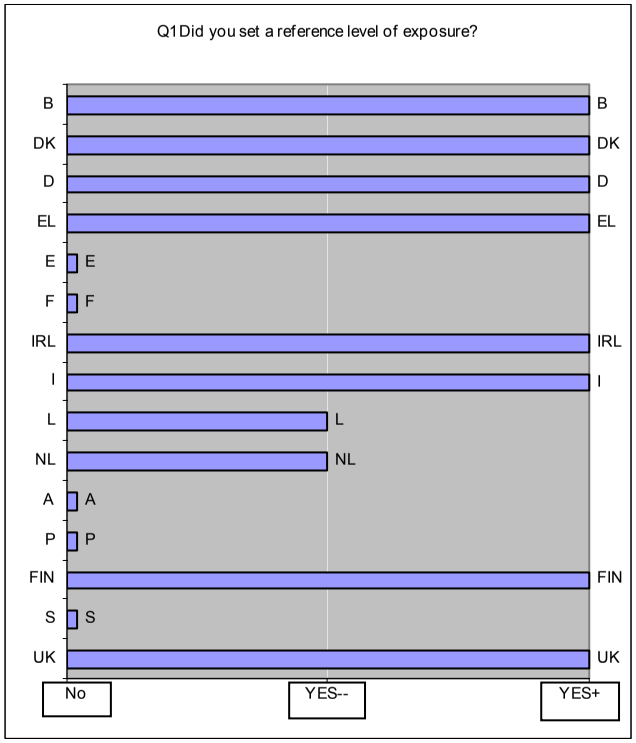
Q13/Q14: -as an intervention?-as a practice?

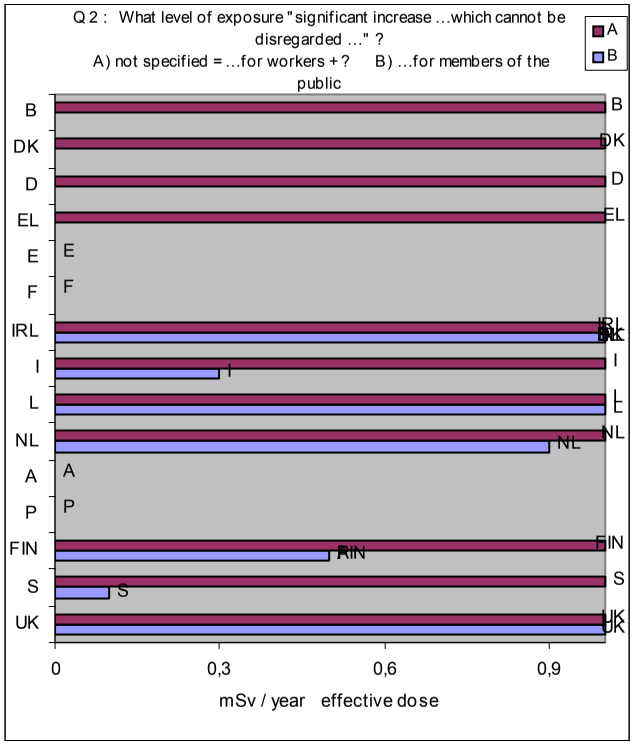
Q15b: Will new projects in the “non nuclear industry” be considered as “practices”?

Q15b: Do you distinguish between “existing and new industries”?

Q16: What about Radon and/or aircrew?How does the regulation of NORM industries relate to other sources (Radon, cosmic radiation (aircrew))







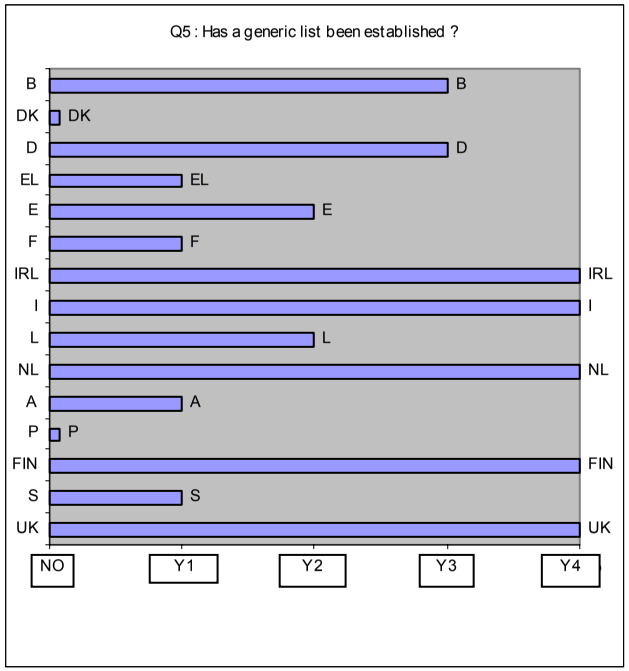


Figure 1 : Directive 96/29
FC = Full Communication
PC = Partial Communication
DM = Comm. Of Draft Measures
No = No Communication

Figure 2 : Question 1
YES+ Yes
YES-- Yes a system exist
No No

Figure 3 : Question 2
A) not specified = … for workers + ?
B) … for members of the public

Figure 4 : Question 5
Y4 = Yes : already in regulation
Y3 = Yes : use of litterature / study
Y2 = Yes : use of EC publi. (RP 88, 95 and/or 107)
Y1 = Yes
No = No answer to that question

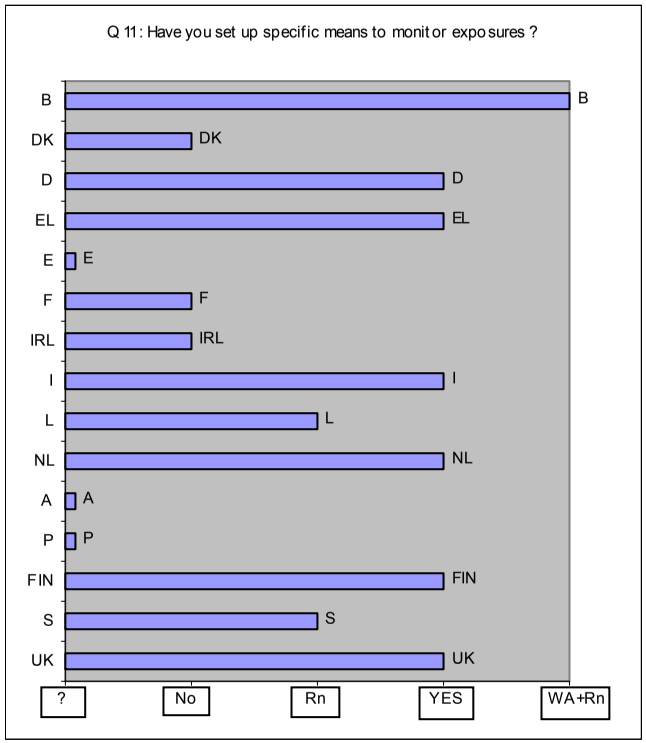


Figure 5: Question 11

WA+Rn =	Yes: both WA + Rn
YES =	Yes: without any detail
Rn =	Yes: only for radon
No =	No
? =	No answer for that question

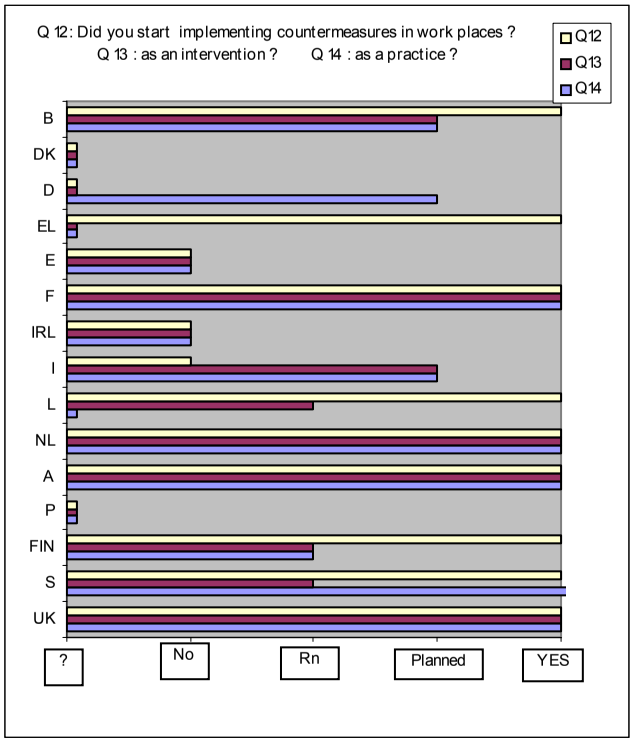


Figure 6: Questions 12 to 14

YES =	Q12 Yes: without any detail
Planned =	Yes: planned in the legislation
Rn =	Yes: only for radon
No =	No
? =	No answer for that question

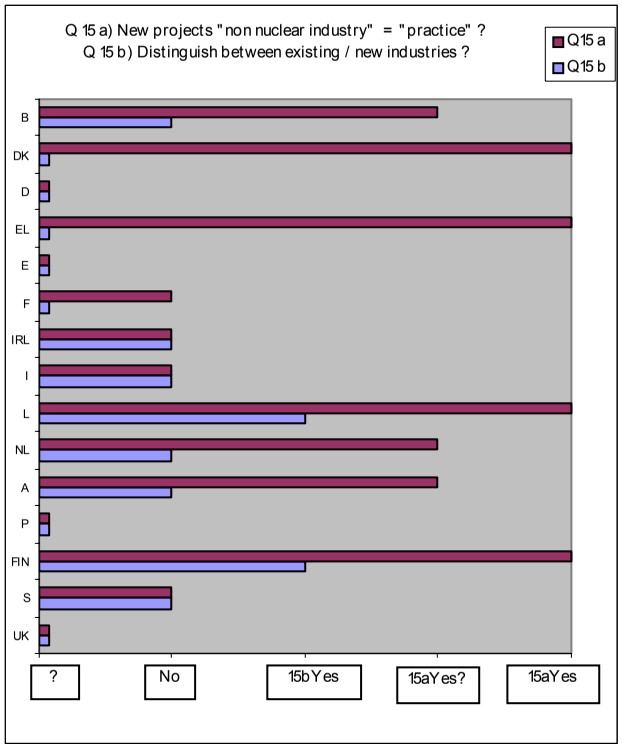


Figure 7: Questions 15a – b

15aYes = Yes Q15a
15aYes? = Q15a Yes ~No because WA # Practices
15bYes = Q15b Yes
No = No Q15a – Q15b
? = No Answer to that question